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Procedures Governing Testing Consent Agreements and Test Rules Under the Toxic Substances Control Act; Interim Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 790 and 799

[OPTS-42052B; FRL 2976-1]

Procedures Governing Testing Consent Agreements and Test Rules Under the Toxic Substances Control Act

AGENCY: Environmental Protection Agency (EPA).

ACTION: Interim final rule.

SUMMARY: This interim final rule amends EPA's regulations for developing and implementing testing requirements under section 4 of the Toxic Substances Control Act (TSCA). These amendments: (1) Provide for the use of enforceable consent agreements to require testing where a consensus exists among EPA, affected manufacturers and/or processors, and interested members of the public; and (2) explain how EPA intends to respond to the testing recommendations of the Interagency Testing Committee (ITC) and the steps that the Agency plans to take to evaluate testing candidates and make a preliminary determination of testing needs. The use of consent agreements will supplement the rulemaking process established under TSCA and expedite the development of the data necessary to determine whether chemical substances and mixtures present an unreasonable risk of injury to health or the environment.

DATES: Effective on July 30, 1986. Submit written comments on or before August 29, 1986.

ADDRESS: Submit written comments identified by the document control number (OPTS-42052B) in triplicate to: TSCA Public Information Office (TS-793), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Rm. E-108, 401 M. St., SW., Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: Edward A. Klein, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, Rm. E-543, 401 M St., SW., Washington, DC 20460.

Toll Free: (800-424-9065),
In Washington, D.C.: (554-1404),
Outside the United States: (Operator—202-554-1404).

SUPPLEMENTARY INFORMATION: This document announces amendments to the procedural regulations in 40 CFR Part 790. which govern the development and implementation of testing requirements under section 4 of the Toxic Substances Control Act (TSCA). The requirements included in these amendments are the outgrowth of a series of meetings between the EPA staff and representatives of the Natural Resources Defense Council (NRDC) and the Chemical Manufacturers Association (CMA) during the spring and summer of 1985. NRDC and CMA assisted EPA in drafting the amendments and endorse their provisions.

The amendments establish procedures for using enforceable consent agreements to require testing under section 4 of the Act. EPA intends to use such consent agreements where a consensus exists among the Agency, affected firms, and interested members of the public about the need for and scope of testing requirements. The Agency believes that, in such circumstances, consent agreements can expedite the initiation of testing and provide safeguards equivalent to those that would apply in the event testing were being conducted pursuant to rule. EPA will continue to invoke the rulemaking procedures specified in the Act in all cases where a consensus does not exist concerning the scope of testing requirements and the Agency believes testing should be required under section 4(a) of the Act.

The amendments also establish procedures for evaluating chemicals under consideration for testing, conducting negotiations and proposing and promulgating test rules. These requirements will help ensure that industry and other interested parties are informed of the steps that EPA will take in the course of reviewing testing candidates and developing testing requirements. The Agency is committed to resolving testing issues expeditiously so that needed testing can begin as soon as possible. These amendments also include the schedule that EPA intends to follow in making testing decisions under TSCA section 4. EPA will list the substances covered by consent agreements in 40 CFR Part 799.

The Interagency Testing Committee (ITC) has independently announced changes in its procedures for making testing recommendations to EPA, which should aid EPA in implementing these amendments. Under section 4(e)(1)(B) of the Act, when the ITC has designated a chemical for action by EPA, the Agency has twelve months either to initiate rulemaking proceedings under section 4(a) or to publish a **Federal Register** notice explaining its reasons for not initiating rulemaking. As explained in its 17th report to the Administrator, published in the **Federal Register** of November 19, 1985 (50 FR 47603), the ITC has created a "recommended with intent-to-designate" category. Under this category, the ITC intends to recommend, but not designate, chemicals that it believes should receive expedited consideration for testing, with an intent to designate the substance or mixture for action at a later time, if deemed necessary by the ITC after a review of additional information.

I. Statutory Background

A major goal of TSCA is to develop test data to determine the effects of chemical substances and mixtures on health and the environment. (TSCA sec. 2(b)(1), 15 U.S.C. 2601(b)(1)). TSCA assigns responsibility for conducting such testing to the manufacturers (including importers) and/or processors of the chemicals involved.

Section 4(a) of the Act, 15 U.S.C. 2603(a), authorizes the Administrator to promulgate rules requiring affected firms to conduct specified tests on chemical substances and mixtures. Before such rules may be promulgated, EPA must make a series of findings identified in section 4(a)(1)(A) and/or (B).

Section 4(b) of the Act requires that each test rule identify the substance or mixture to be tested, specify the studies to be performed, provide standards for the development of test data, and establish deadlines for the submission of test results. Linkages exist between TSCA's testing provisions and other statutory requirements, and thus promulgation of a test rule will trigger certain other provisions of the Act.

Violations of test rules are considered "prohibited acts" under section 15(1) of TSCA. Accordingly, noncompliance with a rule's requirements may give rise to civil and/or criminal penalties under section 16. It may also result in an action to compel adherence to the rule under section 17 or a citizen's enforcement suit under section 20.

Section 4(e) of the Act establishes an Interagency Testing Committee (ITC), composed of representatives from several federal agencies, to assist EPA in identifying chemicals that should receive priority consideration for testing. The statute authorizes the ITC to maintain a list of chemicals that it recommends for testing. The ITC may designate up to 50 of these chemicals at any one time for evaluation by EPA within 12 months of their designation. During the 12-month period following receipt of an ITC designation, EPA must either "initiate a rulemaking proceeding" to require testing or publish a **Federal Register** notice explaining its "reason for not initiating such a proceeding." 15 U.S.C. 2603(e)(1)(B).

II. Development of This Procedural Rule

A. EPA's Use of Negotiated Testing Agreements

During the early years of TSCA's implementation, EPA experienced difficulty in responding to ITC reports in a timely manner. EPA's actions under section 4(e) of the Act were challenged in a suit filed by NRDC, and the court ruled that EPA had failed to discharge its statutory obligation to act on ITC-designated chemicals within 12 months. *NRDC* v. *Costle*, 10 Envtl. L. Rep. (Envtl. L. Inst.) 20274 (S.D.N.Y. Feb. 4, 1980). As a result of the court's ruling, the Agency explored mechanisms for addressing testing issues and initiating needed testing as expeditiously as possible.

Starting in 1979, EPA instituted a procedure of negotiating testing agreements on selected ITC-designated chemicals. On December 6, 1983, NRDC and the AFL–CIO filed suit in the United States District Court for the Southern District of New York to challenge EPA's implementation of TSCA's testing provisions. The plaintiff's claims included an allegation that EPA's use of negotiated testing agreements on ITC-designated chemicals was unlawful because the agreements were voluntary and failed to trigger key statutory provisions applicable to test rules. On August 23, 1984, the District Court held that EPA had failed to discharge its obligations under TSCA by negotiating voluntary testing agreements in lieu of initiating rulemaking on certain chemicals designated by the ITC for priority testing consideration. *NRDC and AFL–CIO* v. *EPA*, 595 F. Supp. 1255 (S.D.N.Y. 1984).

B. Objectives of the EPA–NRDC–CMA Discussions

In March 1985, NRDC and CMA jointly requested an opportunity to meet with EPA representatives to discuss EPA's procedures for developing test data under section 4 of TSCA. An initial meeting of the parties was held on March 28. Thereafter, public meetings were held on April 17, May 13, May 20, and July 19. EPA announced these meetings in the **Federal Register** and established public docket number [OPTS–42069] to contain relevant background materials.

During the meetings, the parties explored the availability of consensual approaches under section 4 that would speed the development of needed data while affording procedural safeguards and protections equivalent to those applicable in the case of test rules. The parties recognized that negotiations could play an important role in resolving testing issues but that significant changes in EPA's procedures for negotiating testing agreements were needed as a result of the District Court decision in *NRDC* v. *EPA, supra*. The parties also recognized the importance of expediting final decisions on testing issues, particularly during rulemaking, so that any needed testing could begin promptly.

As discussions progressed, EPA identified certain basic objectives that it believes the section 4 process should seek to achieve. Among them are: (1) To expeditiously initiate necessary testing; (2) to allow for the use of negotiation and consensus-building where they can accelerate the testing process; (3) to permit adequate public participation in the development of testing programs; (4) to assure that testing is performed using scientifically sound protocols and acceptable laboratory practices; (5) to assure that sanctions can be imposed under TSCA's penalty provisions if the agreed-upon testing is not performed, is unjustifiably delayed, or lapses in testing procedure occur; (6) to permit scientific judgment in implementing required testing programs; and (7) to assure, to the maximum extent feasible, that the procedural safeguards embodied in any consensual mechanism for accomplishing testing are equivalent to the protections included in TSCA's rulemaking provisions.

After discussions with CMA and NRDC, EPA has concluded that enforceable consent agreements can achieve the above objectives where a consensus exists among the interested parties concerning the need for and scope of testing. At the same time, EPA recognizes that the development of test data by rule will remain an important element of its section 4 testing program. Such rules, the Agency has determined, will be used to accomplish necessary testing where the parties, for whatever reason, are unable to reach a timely consensus on how an individual testing program should proceed.

III. Rationale for the Major Elements of EPA's Procedural Rule

In accordance with the above objectives, EPA is promulgating procedures for evaluating testing candidates and conducting negotiations to develop consent agreements where appropriate. EPA is also making necessary conforming changes in its procedures for proposing and promulgating test rules in all other cases where testing is necessary. The schedule that EPA intends to follow in making testing decisions is presented in Appendix A to this rule. The establishment of a recommended with intent-to-designate category by the ITC will help to implement the proposed amendments.

The Agency is issuing these procedures as an interim final rule. The Agency believes that it is unnecessary to issue this rule as a proposal because it is procedural in nature. In addition, it is the result of a negotiated agreement with CNA, NRDC, and EPA and extensive public comment has been received in the development of their rule (see Unit II). The Agency is, nevertheless, providing an opportunity for public comment on this rule in the event persons wish to provide comments on these specific procedures. If these comments result in a need for changes to the rule, EPA will modify the rule as appropriate when it issues a final rule.

A. Recommendations With Intent To Designate

Section 4(e) of TSCA requires the ITC to provide EPA with a list of chemicals which the ITC believes should be considered for testing under section 4(a) of the Act. The ITC is empowered to designate chemicals (not to exceed 50 at any one time) for which EPA must, within 12 months, either initiate rulemaking under section 4(a) or publish its reasons for not doing so. In addition, the statute allows the ITC to recommend an unlimited number of chemicals for testing without designating them for EPA action by the 12-month deadline.

Up to now, when the ITC has identified a chemical substance or mixture that it believes should receive expedited consideration for testing, the ITC generally has designated the substance or mixture for action by EPA within 12 months. Because of the 12-month deadline, EPA must set in motion the preparation of a rulemaking proposal soon after receiving an ITC designation. As a result, insufficient time exists for meaningful negotiation and, even where agreement can be reached, the Agency may be forced to initiate rule development activities in the event that negotiation will be unsuccessful. Furthermore, while section 8(a) and 8(d) reports often help to focus and sometimes satisfy the Agency's information needs, they are not received and compiled until 4 months after receipt of the ITC's report. These submissions are therefore frequently unavailable in time to be fully considered in EPA's preliminary judgments about the need for and scope of testing.

The ITC decided to introduce a new procedure, which is announced in its 17th Report, published in the **Federal Register** of November 19, 1985 (50 FR 47603). Under the new procedure,

chemicals that the ITC believes should receive expedited testing consideration may initially be recommended, but not designated, for action by EPA. The ITC report containing these recommendations would include a statement that the ITC intends to designate the substance or mixture for action by EPA at a later date. The ITC's subsequent decision to either designate or not designate the substance would be based on the ITC's review of 8(a) and 8(d) data and other relevant information. After a substance or mixture has been designated, section 4(e)(1)(B) of TSCA would require EPA, within 12 months, either to initiate rulemaking proceedings or publish a statement of its reasons for not initiating such proceedings.

The intent-to-designate procedure will have several advantages. First, EPA will no longer need to negotiate and prepare for rulemaking simultaneously, but can initially focus on negotiation and turn its attention to rulemaking should negotiation prove unproductive. Second, ITC will have access to section 8(a) and 8(d) information to factor into its decision whether to designate a substance or mixture. Third, industry will have incentives to negotiate constructively early in the section 4 process since, in the absence of agreement, negotiations will be terminated and EPA will proceed with rulemaking.

Although the intent-to-designate procedure gives EPA additional time to take action on ITC-designated chemicals, the procedure will ultimately expedite testing decisions and the development of data. As described below, the Agency intends to finalize consent agreements by week 50 following an ITC recommendation if consensus can be achieved. If negotiations fail to produce consensus and rulemaking is required, EPA intends to propose test rules by week 62, and to finalize such rules by week 108. Thus, the net effect of the intent-to-designate procedure should be to accelerate testing decisions and thereby expedite the initiation of testing.

B. Use of Consent Agreements

1. *Value of non-rulemaking approaches.* During its discussions with NRDC and CMA, the Agency was initially uncertain about the best procedural mechanism for implementing agreed-upon testing programs. One possibility that received careful consideration was incorporating negotiation into the rulemaking process with the aim of promulgating an agreed-upon test rule. Upon close study, however, this approach presented a number of problems and ultimately was judged to be less effective than the use of enforceable consent agreements.

First, the statute provides the section 4(a) rules must be supported by a number of findings. There may be instances where the basis for these findings is in dispute even though manufacturers or processors are prepared to conduct testing. Resolution of such disputed issues during the rulemaking process might require considerable effort and could delay testing even though there is underlying agreement on the studies to be conducted.

Second, experience has shown that considerable time may be needed to prepare a rulemaking proposal and support documents, solicit comments, respond to the issues raised by comments, and publish a final rule. Where the parties have agreed on an acceptable testing program, notice-and-comment procedures and extended Agency review may unnecessarily delay the start of testing.

Third, under section 4 of TSCA, test rules will be applicable to all of the manufacturers and/or processors of the test chemical. However, where a consortium of firms is prepared to conduct and finance testing, consent agreements would not have to be signed by all other manufacturers or processors of the test chemical. Thus, it would be possible to proceed with testing on a consensual basis even though one or more firms are unwilling to participate in testing or reimbursement.

Because consent agreements can be finalized more promptly than rules, EPA believes that they represent a more expeditious mechanism for initiating testing while affording equivalent procedural safeguards. EPA will, however, proceed with rulemaking whenever it believes that testing would be required under section 4(a) and negotiations do not achieve a consensus. To assure that the Agency has adequate time to prepare a rulemaking proposal, it will terminate negotiations after 10 weeks unless continued negotiation is likely to result in a draft agreement within an additional 4 weeks. During this additional 4 weeks, EPA must prepare a draft consent agreement that reflects an apparent consensus among the parties. If EPA has not prepared a draft consent agreement embodying an apparent consensus by the end of this 4-week period, EPA will end the negotiations and proceed with rulemaking.

In the event that EPA proceeds with rulemaking, the Agency intends to complete the rulemaking process as expeditiously as possible. As indicated in Appendix A to the procedural rule, EPA intends to publish a rulemaking proposal by week 62 following receipt of an ITC recommendation, and to publish a final rule or a notice terminating the rulemaking proceeding by week 108.

2. *Enforceability of consent agreements.* To serve as a viable alternative to rulemaking, consent agreements must be enforceable on the same basis as test rules. For this reason, § 790.65 of this rule provides that consent agreements requiring testing will be treated as "orders issued under section 4" for purposes of section 15(1) of TSCA, which defines conduct that will be considered a "prohibited act." Under this approach, manufacturers and/or processors who violate consent agreements will be subject to criminal and/or civil liability under section 16 of TSCA. In addition, EPA can invoke the remedies available under section 17 of TSCA, including seeking an injunction to compel adherence to the requirements of the consent agreement. Citizens can also file civil actions to enforce consent agreements as prescribed in section 20 of the Act.

The Act does not specifically address the use of consent agreements to implement consensual testing programs. EPA believes, however, that a sound legal basis exists for invoking TSCA's enforcement provisions against firms that violate consent agreements.

The rulemaking record for this rule contains an analysis of the legal authority for enforcing consent agreements issued under section 4 of TSCA. As this analysis concludes, there is a well-recognized policy in favor of consent orders since they minimize the need for adversary proceedings and conserve the resources of the parties. A consent agreement will normally be upheld in court if it is in the public interest and will further the basic purposes of the relevant statute. In the event one or more provisions of a consent agreement issued under section 4 are determined to be unenforceable by a court, EPA will then either initiate a rulemaking proceeding or publish in the **Federal Register** the Agency's reason for not initiating such a proceeding.

In this instance, EPA believes that consent agreements requiring testing under section 4 will further one of TSCA's basic policies that "adequate data should be developed with respect to the effects of chemical substances and mixtures on health and the environment." Section 2(b)(1) of TSCA, 15 U.S.C. 2601(b)(1). EPA also believes that the safeguards and procedures established by this rule will assure that the development of consent orders is

compatible with the specific objectives of section 4.

One of the fundamental principles governing consent agreements is that parties who voluntarily accept their requirements waive their right to challenge the legal justification for those requirements. In accordance with this principle, § 790.60(a)(3) of the rule provides that each consent agreement requiring testing will contain a provision stating that the signatories to the agreement acknowledge that violations of its requirements will constitute a "prohibited act" under section 15(1) of the Act. In view of this provision, EPA believes that a firm that violates a consent agreement will be held to have waived its right to challenge the Agency's authority to assess penalties.

Because violations of consent agreements will be deemed "prohibited acts" under section 15(1), they will also constitute conduct "in violation of this Act" under section 20(a)(1) of TSCA. Thus, failure to comply with the requirements of a consent agreement could result in a citizens' civil action under section 20(a)(1). Before a court can entertain such an action, however, the other statutory prerequisites for a citizens' suit will have to be satisfied. For example, in accordance with section 20(b)(1), the prospective plaintiff will have to give EPA notice of its intent to sue at least 60 days before filing a complaint, and no suit can be maintained if EPA has commenced and is diligently prosecuting a proceeding to require compliance with the consent agreement under section 16(a)(2).

3. *Public participation in negotiations.* EPA recognizes the importance of adequate public participation in framing a consent agreement's provisions. Accordingly, the procedural rule contains provisions to assure that the views of interested parties are taken into account during the negotiation process.

Under § 790.22, EPA will initiate negotiations by publishing a **Federal Register** notice which invites persons interested in participating in or monitoring negotiations to contact the Agency in writing. The deadline for making such requests will be EPA's "course setting" meeting, which is expected to occur during week 22 following receipt of an ITC report. Individuals and groups who respond to EPA's notice by the date of this meeting will have the status of "interested parties" and will be afforded opportunities to participate in the negotiation process. The rule provides that all negotiating meetings will be open to members of the public, and minutes of each meeting will be prepared by EPA and placed in the public docket. In addition, the Agency will advise interested parties of meeting dates and circulate meeting minutes, testing proposals, background documents and other relevant materials. Finally, where tentative agreement is reached on an acceptable testing program, a draft consent agreement will be made available for comment by interested parties and, if necessary, EPA will hold a public meeting to discuss any comments that have been received. (Please note: EPA will not reimburse costs incurred by nonEPA participants in the consent agreement negotiation process.)

Consent agreements will only be used where a consensus exists concerning the need for and scope of testing. In the absence of consensus, EPA will proceed with rulemaking. The notice-and-comment procedures associated with rulemaking—and the accompanying availability of judicial review under section 19 of TSCA—will provide a suitable vehicle for resolving differences of opinion.

EPA does not intend, however, to give interested parties an open-ended "veto" over draft consent agreements. Such a veto would allow generalized criticisms of a testing program (for example, that the program is "inadequate to evaluate the chemical's health effects") to nullify the results of negotiations and force EPA to initiate rulemaking. To avoid this problem, § 790.24(a)(2) provides that a draft consent agreement negotiated by EPA and affected firms will be rejected only where interested persons participating in the negotiations have submitted timely written objections. In addition, § 790.24(b) of the rule states that EPA may override objections that the Agency concludes (a) are not made in good faith, (b) do not involve the adequacy of the proposed testing program or other features of the agreement that may affect EPA's ability to fulfill the goals and purposes of the Act, or (c) are not accompanied by a specific explanation of the grounds on which the draft agreement is considered objectionable. The Agency's review of objections, should they be submitted, is intended solely to determine whether they meet these criteria. Once objections meet the threshold requirements of this rule, EPA will conclude that no consensus exists and will proceed with rulemaking under section 4(a) of the Act to require such testing as the Agency finds necessary and consistent with the provisions of TSCA.

To facilitate public oversight of EPA's activities under TSCA, each consent agreement will be accompanied by a written explanation of its basis. Under § 790.60(c) of the interim rule, this document will summarize any ITC testing recommendations for the chemical involved, describe the objectives of the testing to be conducted and the rationale for the selection of tests, and briefly outline the use and exposure characteristics of the test chemical. This document, along with notice of the availability of the consent agreement, will be published in the **Federal Register** and, for ITC-designated chemicals, will constitute the statement of EPA's "reason" for not initiating rulemaking required by section 4(e)(1)(B) of the Act.

4. *Other aspects of equivalence between consent agreements and rules.* In addition to providing for enforceability and public participation in the negotiation process, EPA believes that consent agreements must be equivalent to test rules in other respects in order to satisfy the requirements of TSCA. Section 790.60 of the amended procedural rule will accomplish this goal. Among other things, this provision assures that consent agreements contain the following requirements:

a. *Data quality.* Consent agreements will contain: (1) A specification of the technical or commercial grade of the test substance or mixture, (2) standards for the development of test data, (3) a requirement to conduct testing in accordance with EPA's Good Laboratory Practice (GLP) regulations, (4) a requirement to submit a study plan to EPA prior to the initiation of testing, and (5) a provision recognizing EPA's authority to inspect laboratories and audit studies in accordance with the requirements of section 11 of the Act. These provisions will assure that testing conducted under consent agreements is performed using scientifically sound protocols and acceptable laboratory practices.

Section 790.60(b) of the rule provides that the "test standards" included in consent agreements must be modeled on certain well-recognized methodologies for health and environmental effects testing, including the test guidelines developed by EPA under TSCA and the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the test guidelines published by the Organization for Economic Cooperation and Development (OECD). It provides further that during the negotiation of consent agreements, EPA will initially propose suitable guidelines as required testing standards; affected firms or other interested parties may then propose alternative methodologies or modifications to these guidelines where

they believe such alternatives would develop more reliable and adequate data on the specific test chemical. This is the same procedure that EPA now uses to establish "standards for the development of data" on substances and mixtures that will be tested by rule. (See Subpart C of 40 CFR Part 790.) Thus, EPA is confident that the methodologies used for testing conducted under consent agreements will be equivalent to those included in test rules promulgated under section 4(a).

b. *Schedules.* Each consent agreement will contain enforceable schedules for initiating testing and submitting interim progress and/or final reports to EPA. Thus, effective mechanisms will exist to assure that test data are developed and reported in a timely manner.

c. *Export notification.* Section 12(b) of TSCA requires persons who export or intend to export certain chemical substances or mixtures to notify the Agency of such export. EPA promulgated regulations interpreting these export notification requirements in 40 CFR Part 707. The export notification requirements are triggered whenever EPA takes certain actions on a substance or mixture. One of these triggering actions is a requirement for the submission of data under section 4 of TSCA. The Agency has recently interpreted the section 12(b) requirements to apply to substances subject to final Phase I test rules, as opposed to proposed section 4 rules. (See Statement of clarification, 49 FR 45581, November 19, 1984.)

For the purposes of TSCA export notification requirements, the Agency considers a final testing consent agreement to be the equivalent of a final section 4 test rule. It is an equivalent data gathering requirement under section 4 of TSCA because it represents the Agency's commitment to proceed with data collection with respect to specific substances. Therefore, the Agency has determined that consent agreements will trigger TSCA section 12(b) export notification requirements. Persons who export or intend to export a substance which is the subject of a final consent agreement will be subject to section 12(b). As with similar actions that trigger section 12(b) (for example a consent order under section 5), export notificaton requirements apply to persons who sign a consent agreement as well as to any other persons who exports or intends to export any substance covered by an agreement.

Each consent agreement will state that the manufacturers and/or processors signing the agreement will comply with the notification requirements of section 12(b) if they export or intend to export a subject substance or mixture. The agreement will cite the regulations codified at 40 CFR Part 707 and will further state that any other person who exports or intends to export a subject substance or mixture is also subject to these export notification requirements.

In the **Federal Register** notice announcing a final consent agreement, the Agency will state that any person who exports or intends to export a substance or mixture covered by the consent agreement is subject to section 12(b) export notification provisions. The notice will specifically refer the reader to regulations codified at 40 CFR Part 707. It will also automatically add the substance(s) to 40 CFR Part 799, Subpart C. See Unit **VI. Modifications to 40 CFR Part 799** of this notice.

These actions will insure proper public notification of this generally applicable export notification requirement. In addition, the Office of Toxic Substances will add the subject chemicals to the list of substances covered by section 12(b). This list is published as part of "A Guide for Chemical Importers/Exporters", available from the OTS TSCA Assistance Office.

d. *Data disclosure.* Each consent agreement will provide that the results of testing will be announced to the public in accordance with the procedures specified in section 4(d) of the Act and that the disclosure of data will be governed by section 14(b) of the Act. Thus, EPA will promptly publish in the **Federal Register** a summary of test data and notice of the availability of such data for public review, as required by section 4(d). In addition, the results of testing will be considered "health and safety studies" under section 14(b), and thus the assertion of confidentiality claims will be limited in accordance with this provision's requirements.

e. *Application of testing requirements to significant new use rules.* Each consent agreement will contain a requirement that, in the event EPA promulgates a significant new use rule (SNUR) applicable to the test chemical under section 5(a)(2), the agreement will have the status of a test rule for purposes of section 5(b)(1)(A). Under section 5(b)(1)(A), if EPA promulgates a SNUR for a chemical under section 5(a)(2) and that chemical is subject to a section 4 test rule, manufacturers and/or processors must submit the test data required by the section 4 test rule at the time they file a SNUR notice under section 5(a)(2). Thus, manufacturers and/or processors subject to a consent agreement will be required to submit the results of testing to EPA at the time they file a SNUR notice under section 5(a)(2).

Manufacturers and/or processors of the test chemical who do not sign the consent agreement will be subject to EPA's SNUR and, accordingly, would be required to submit a SNUR notice before manufacturing or processing the chemical for a significant new use. These notices would not, however, expressly be required to include the data that must be developed under the consent agreement. Nevertheless, in such cases, EPA will issue, when appropriate, others under section 5(e) of the Act to prohibit or restrict the activities described in the SNUR notice pending the development and submission of the test data required under the consent agreement.

f. *Modification of consent agreements.* As in the case of test rules, consent agreements may need to be modified as a result of unforeseen developments which occur while testing is underway. Section 790.68 establishes procedures for making such modifications. Changes in test standards or schedules will be handled in the same manner under both consent agreements and test rules. Except as described here, EPA will seek public comment on all substantive changes in test standards or schedules. Requests for modification of standards or schedules will be acted on without an opportunity for public comment only if: (1) EPA believes that immediate action is necessary to preserve the accuracy or validity of an ongoing study, or (2) EPA determines that the proposed modification clearly does not raise any substantive issues.

A different approach will be followed where the proposed modification involves the scope of the testing program required under a consent agreement. Since this modification will result in the addition or elimination of particular studies, the procedures for its adoption should parallel those used to develop the original consent agreement. Accordingly, EPA will publish a **Federal Register** notice describing the proposed modification and soliciting public comment where, on its own initiative or based upon requests from members of the public, it determines that new issues have been raised that warrant reconsideration of the scope of testing. EPA will thereafter reopen negotiations where, based on the written comments submitted to the Agency, it concludes that there are differences of opinion concerning the proposed changes in the testing program. If a consensus in support of the proposed modification does not exist at the conclusion of negotiations, EPA will initiate

rulemaking where it concludes that more testing than the consent agreement requires is necessary. Normally, the consent agreement will remain in effect while rulemaking proceedings are underway. Where EPA determines that particular tests required by the agreement are or may be unnecessary in view of the requirements of the proposed rule, however, these tests would not have to be performed pending the completion of the rulemaking process.

5. *Compatibility with the district court's decision in NRDC v. EPA.* In the discussions preceding development of this procedural rule, EPA, NRDC, and CMA concluded that the court's decision in *NRDC v. EPA*, 595 F. Supp. 1255 (S.D.N.Y. 1984) did not preclude the use of non-rulemaking mechanisms for requiring testing where they provide safeguards equivalent to those provided by the rulemaking process established by TSCA. The negotiated testing agreements invalidated by the court in that case were not enforceable and failed to trigger certain other TSCA provisions that would take effect upon the issuance of a test rule. In addition, interested parties had less opportunity to participate in the negotiations process than EPA now plans to afford. EPA therefore believes, and NRDC and CMA have agreed, that the use of consent agreements in accordance with this procedural rule is an acceptable method of discharging EPA's obligations under section 4 of TSCA.

C. Schedules for Developing Consent Agreements and Test Rules

One of EPA's main objectives in implementing section 4 of TSCA is the speedy development of data where testing is necessary. To accomplish this objective, it is important to establish an expeditious timetable for the various steps in evaluating testing candidates, beginning and completing negotiations to develop consent agreements where appropriate, and proposing and promulgating test rules in the remaining instances where testing can be required under section 4(a). Such a timetable is therefore included in Appendix A to the procedural rule. Where the deadlines in the schedule are imposed by the statute, they are binding on EPA and will be observed by the Agency. The remaining dates represent targets that EPA intends to meet. This schedule is based on what EPA currently beleives are reasonable target dates. As EPA gains experience with the process and determines the feasibility of these schedules, it may adjust the schedules accordingly. EPA will solicit public comment before implementing any changes in the schedule.

IV. EPA's Use of the Negotiated Consent Agreement Process

When negotiation can promptly lead to a consensus on testing to be performed on a chemical, the initiation of testing and the ultimate availability of test data will be accomplished substantially sooner than if a test rule were developed and promulgated. Therfore, EPA considers the negotiated consent agreement process described in this procedural rule to be appropriate in all cases where the Agency believes that negotiation can be conducted in a timely and efficient manner and has a reasonable likelihood of reaching consensus within the schedule presented in Appendix A to the rule. EPA also must be able to comply with any statutory or court-ordered deadlines for initiating a test rule proceeding should the Agency conclude that testing should be required but negotiations fail to reach a consensus. EPA believes that the above criteria generally will be met for chemical substances and mixtures recommended for testing consideration by the ITC (but without immediate designation for EPA action within 1 year) and for other substances and mixtures that EPA may identify as testing candidates separate from the ITC process. EPA intends to use the negotiation process described in § 790.22(b) of this rule in such cases.

However, EPA reserves the right to proceed directly with a rulemaking proceeding in cases where the Agency believes the above criteria are not met. Such instances may include chemicals designated by the ITC for 1-year response at the time of their initial recommendation, individual substance or mixture testing requirements which EPA believes unlikely to be successfully negotiated based on preliminary discussions with manufacturers and/or processors, and certain types of category or generic test rules for which the number of interested parties and/or their inability to be identified on a chemical-specific basis may make the negotiation procedures described in this rule infeasible or unlikely to yield consensus in a timely manner.

V. Other Modifications to 40 CFR Part 790

In addition to the amendments providing for the use of consent agreements, EPA is making the following modifications to existing provisions of 40 CFR Part 790.

A. Submission of Information

Under submission of information requirements (§ 790.5), EPA is requiring that six copies be provided to EPA for all submissions required under consent agreements or test rules. All submissions should be addressed "Attention: TSCA section 4."

B. Submission of Study Plans

1. Under submission of study plans (§ 790.40), EPA is requiring that study plans be submitted to EPA no later than 45 days before the initiation of each test. This additional time is necessary to allow the Agency sufficient time to arrange for laboratory inspections and data audits.

2. Under submission of study plans (§ 790.40), EPA is requiring the submission of final study plans for tests required under two-phase rules. This requirement allows EPA to obtain revised study plans incorporating the proposed study plans and any modifications adopted in the phase II final rule. The final study plans must be submitted no later than 45 days before the initiation of each test.

VI. Modifications to 40 CFR Part 799

Part 799 of 40 CFR identifies those substances and mixtures that are the subject of TSCA section 4 testing requirements. In this document the Agency is adding two technical, clarifying amendments to Part 799. The first provision is a new § 799.19 Chemical Imports and Exports being added to Subpart A. The purpose of this new section is to notify the reader of the CFR that substances listed in Part 799 are covered by the TSCA section 12(b) regulations regarding export notification. It provides the reader of the CFR with a specific cross reference to Part 707.

The second provision adds a new Subpart C. This new subpart will contain a comprehensive listing by Chemical Abstracts Service (CAS) Registry Number of substances covered by consent testing agreements. The listing will also provide a reference to the **Federal Register** notice regarding such consent agreements. The purpose of this amendment is to aid exporters of chemical substances in identifying those substances for which they have notification obligations. Notices of consent testing agreements will appear in the **Federal Register**. However, there is no mechanism for creating a permanent, comprehensive record of the substances covered by these agreements without the existence of this new subpart.

VII. Rulemaking Record

EPA has established a public record for this rulemaking, docket number [OPTS–42052B], which contains the following information:

(1) **Federal Register** notices pertaining to this rule consisting of:

(a) Rule concerning single-phase test rule development and exemption procedures.

(b) Rule concerning two-phase test rule development and exemption procedures.

(2) Communications including:

(a) Written public comments and letters.

(b) Contact reports of telephone conversations.

(c) Meeting summaries.

This record, which includes basic information considered by the Agency in developing this rule and appropriate **Federal Register** notices, is available for inspection in the OPTS Reading Room, Rm. E–107, 401 M St., SW., Washington, DC from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

VIII. Other Regulatory Requirements

A. Executive Order 12291

Under Executive Order 12291, EPA must judge whether a regulation is "Major" and, therefore, subject to the requirement of a Regulatory Impact Analysis. This rule on procedures governing consent agreements and test rules under section 4 of TSCA is not major because it does not meet any of the criteria set forth in section 1(b) of the Order. The regulation is a procedural rule.

This rule was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291. Any written comments from OMB to EPA, and any EPA response to those comments, will be included in the rulemaking record.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act (15 U.S.C. 601 *et seq.*, Pub. L. 96–354, Sept. 19, 1980), EPA is certifying that this rule will not have a significant impact on a substantial number of small entities.

The procedural amendments described in this rule provide an alternative to rulemaking and are expected to reduce the administrative and financial burden which testing rules might otherwise impose on regulated industries.

C. Paperwork Reduction Act

The information collection requirements contained in this rule have been approved by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.*, and have been assigned OMB control number 2070–0033.

List of Subjects in 40 CFR Parts 790 and 799

Test procedures, Exemptions, Environmental protection, Hazardous substances, Chemicals, Chemical export.

Dated: June 23, 1986.

Lee M. Thomas,

Administrator.

Therefore, 40 CFR Parts 790 and 799 are amended as follows:

1. Part 790 is amended as follows:

a. The authority citation for Part 790 continues to read as follows:

Authority: 15 U.S.C. 2603.

b. By revising the heading for Part 790 to read as follows:

PART 790—PROCEDURES GOVERNING TESTING CONSENT AGREEMENTS AND TEST RULES

c. In Subpart A:

i. Section 790.1 is revised to read as follows:

§ 790.1 Scope, purpose, and authority.

(a) This part establishes procedures for gathering information, conducting negotiations, and developing and implementing test rules or consent agreements on chemical substances and mixtures under section 4 of TSCA.

(b) Section 4 of the Act authorizes EPA to require manufacturers and processors of chemical substances and mixtures to test these chemicals to determine whether they have adverse health or environmental effects. Section 4 (a) empowers the Agency to promulgate rules which require such testing. In addition, EPA has implied authority to enter into enforceable consent agreements requiring testing where they provide procedural safeguards equivalent to those that apply where testing is conducted by rule.

(c) EPA intends to use enforceable consent agreements to accomplish testing where a consensus exists among EPA, affected manufacturers and/or processors, and interested members of the public concerning the need for and scope of testing. If such a consensus does not exist and the Agency believes that it can make the findings specified in section 4(a), EPA will initiate proceedings to promulgate test rules which will be codified in Part 799 of this chapter.

(d) Appendix A to this part presents timetables for various steps in the evaluation of chemicals under consideration for testing, the initiation and completion of negotiations to develop consent agreements, and the proposal and promulgation of test rules. All deadlines which are imposed by the Act are binding on EPA and will be observed by the Agency. The remaining deadlines represent target dates that EPA intends to meet.

ii. Section 790.2 is revised to read as follows:

§ 790.2 Applicability.

This part is applicable to manufacturers and processors of chemical substances or mixtures who are subject to the testing requirements of a consent agreement or a rule under section 4(a) of the Act. The procedures for test rules are applicable to each test rule in Part 799 or this Chapter unless otherwise stated in specific test rules in Part 799 of this Chapter.

iii. Section 790.3 is amended by revising the definition for "sponsor" to read as follows:

§ 790.3 Definitions.

* * * * *

"Sponsor" means the person or persons who design, direct and finance the testing of a substance or mixture.

* * * * *

iv. Section 790.5 is amended by revising paragraphs (a), (b), and (c) to read as follows:

§ 790.5 Submission of information.

(a) All submissions to EPA under this part must bear the Code of Federal Regulations (CFR) section number of the subject chemical test rule, e.g., § 799.4400 1,1,1-Trichloroethane, or indicate the identity of the consent agreement. For all submissions under this part, six copies must be provided to EPA.

(b) Submissions containing confidential business information must be addressed to:

Attention: TSCA Section 4,
Document Control Office (TS–793),
Office of Pesticides and Toxic Substances,
Environmental Protection Agency,
Rm. E–201,
401 M St., SW.,
Washington, DC 20460.

(c) Submissions not containing confidential business information must be addressed to:

Attention: TSCA Section 4,
TSCA Public Information Office (TS–793),
Office of Pesticides and Toxic Substances,
Environmental Protection Agency,
Rm. E–108,
401 M. St., SW.,

Washington, DC 20460.

* * * * *

(Approved by the Office of Management and Budget under control No. 2070-0033)

v. Section 790.7 is amended by revising paragraph (a) and the introductory text of paragraph (c) to read as follows:

§ 790.7 Confidentiality.

(a) Any person subject to the requirements of a consent agreement or a test rule under section 4 of the Act may assert a claim of confidentiality for certain information submitted to EPA in response to the consent agreement or the test rule. Any information claimed as confidential will be treated in accordance with the procedures in Part 2 of this title and section 14 of the Act. Failure to assert a claim of confidentiality at the time the information is submitted will result in the information being made available to the public without further notice to the submitter.

* * * * *

(c) If a person asserts a claim of confidentiality for study plan information described in §§ 790.50(c)(1)(iii)(D), (iv), (v), and (vi) and 790.62(b)(6), (7), (8), (9), and (10), the person must provide a detailed written substantiation of the claim by answering the questions in this paragraph. Failure to provide written substantiation at the time the study plan information is submitted will be considered a waiver of the claim of confidentiality, and the study plan information will be disclosed to the public without further notice.

* * * * *

d. In Subpart B:

i. By redesignating existing Subpart B as Subpart C and revising the heading to read as follows:

Subpart C—Implementation, Enforcement, and Modification of Test Rules

ii. By redesignating §§ 790.20, 790.22, 790.25, 790.28, 790.30, 790.32, 790.35, and 790.39 as §§ 790.40, 790.42, 790.45, 790.48, 790.50, 790.52, 790.55, and 790.59, respectively, and changing all references throughout the part accordingly.

iii. Section 790.40 is amended by revising paragraph (a) to read as follows:

§ 790.40 Promulgation of test rules.

(a) If EPA determines that it is necessary to test a chemical substance or mixture by rule under section 4 of the Act, it will promulgate a test rule in Part 799 of this chapter.

* * * * *

iv. Section 790.50 is amended by revising paragraph (a) (1) and (2) to read as follows:

§ 790.50 Submission of study plans.

(a) *Who must submit study plans.* (1) Persons who notify EPA of their intent to conduct tests in compliance with the requirements of a single-phase rule as described in § 790.40(b)(1) must submit study plans for those tests no later than 45 days before the initiation of each of these tests.

(2) Persons who notify EPA of their intent to conduct tests in compliance with the requirements of a Phase I test rule as described in § 790.40(b)(2) must submit the following:

(i) Proposed study plans for those tests must be submitted on or before 90 days after the effective date of the Phase I rule; or, for processors complying with the notice described in § 790.40(b)(2), 90 days after the publication date of that notice; or 60 days after the date manufacture or processing begins as described in § 790.45(d), as appropriate; and

(ii) Final study plans for those tests must be submitted no later than 45 days before the initiation of each of those tests.

* * * * *

(Approved by the Office of Management and Budget under control no. 2070-0033)

v. By adding a new Subpart B, to read as follows:

Subpart B—Procedures for Developing Consent Agreements and Test Rules

Sec.

Subpart B—Procedures for Developing Consent Agreements and Test Rules

§ 790.20 Recommendation and designation of testing candidates by the ITC.

(a) *Recommendations with intent to designate.* The ITC has advised EPA that it will discharge its responsibilities under section 4(e) of the Act in the following manner:

(1) When the ITC identifies a chemical substance or mixture that it believes should receive expedited consideration by EPA for testing, the ITC may add the substance or mixture to its list of chemicals recommended for testing and include a statement that the ITC intends to designate the substance or mixture for action by EPA in accordance with section 4(e)(1)(B) of the Act.

(2) Chemical substances or mixtures selected for expedited review under paragraph (a)(1) of this section may, at a later time, be designated for EPA action within 12 months of such designation. The ITC's subsequent decision would be based on the ITC's review of TSCA sections 8(a) and 8(d) data and other relevant information.

(3) Where the ITC concludes that a substance or mixture warrants testing consideration but that expedited EPA review of testing needs is not justified, the ITC will add the substance or mixture to its list of testing recommendations without expressing an intent to designate the substance or mixture for EPA action in accordance with section 4(e)(1)(B) of the Act.

(4) The ITC reserves its right to designate any chemical that it determines the Agency should, within 12 months of the data first designated, initiate a proceeding under section 4(a) of the Act.

(b) *EPA consideration of ITC recommendations.* (1) Where a substance or mixture is designated for EPA action under section 4(e)(1)(B) of the Act, the Agency will take either one of the following actions within 12 months after receiving the ITC designation:

(i) Initiate rulemaking proceedings under section 4(a) of the Act.

(ii) Publish a **Federal Register** notice explaining the Agency's reasons for not initiating such rulemaking proceedings. EPA may conclude that rulemaking proceedings under section 4(a) of the Act are unnecessary if it determines that the findings specified in section 4(a) of the Act cannot be made or if the Agency has entered into a consent agreement requiring testing in accordance with the provisions of this Subpart.

(2) Where a substance or mixture has been recommended for testing by the ITC without an intent to designate, EPA will use its best efforts to act on the ITC's recommendations as rapidly as possible consistent with its other priorities and responsiblities. EPA may respond to the ITC's recommendations either by:

(i) Initiating rulemaking proceedings under section 4(a) of the Act.

(ii) Publishing a **Federal Register** notice explaining the Agency's reasons for concluding that testing is unnecessary.

(iii) Entering into a consent agreement in accordance with this Subpart.

§ 790.22 Procedures for gathering information and negotiating consent agreements on chemicals which the ITC has recommended for testing with an intent to designate.

(a) *Preliminary EPA evaluation.* Following receipt of an ITC report containing a recommendation with an intent to designate, EPA will use the following procedure for completing a preliminary evaluation of testing needs.

Appendix A to this Part presents the schedule that EPA intends to follow for this purpose.

(1) EPA will publish the ITC report in the **Federal Register** and announce that interested persons have 30 days to submit comments on the ITC's testing recommendations.

(2) EPA will publish a **Federal Register** notice adding all ITC-recommended chemicals to the automatic reporting provisions of its rules under sections 8(a) and 8(d) of the Act (40 CFR Parts 712 and 716).

(3) EPA will hold a public "focus meeting" to discuss the ITC's testing recommendations and obtain comments and information from interested parties.

(4) EPA will evaluate submissions received under the sections 8(a) and 8(d) reporting requirements, comments filed on the ITC's recommendations, and other information and data compiled by the Agency.

(5) EPA will make a preliminary staff determination of the need for testing and, where testing appears warranted, will tentatively select the studies to be performed.

(6) EPA will hold a public meeting to announce its preliminary testing determinations.

(b) *Negotiation procedures for consent agreements.* Where EPA believes that testing is necessary, the Agency will explore whether a consent agreement can be negotiated that satisfies the testing needs identified by the Agency. EPA will use the following procedures for negotiating, formulating and accepting consent agreements. Appendix A to this Part presents the schedule that EPA intends to follow for this purpose.

(1) In the **Federal Register** notice described in paragraph (a)(1) of this section, EPA will explain its procedures and timetable for negotiating consent agreements and invite persons interested in participating in or monitoring negotiations to contact the Agency in writing.

(2) Persons who respond to EPA's notice by the announced date of the Agency's course-setting meeting will be deemed "interested parties" for purposes of any negotiations that EPA conducts.

(3) Following the course-setting meeting announcing EPA's preliminary testing determinations, the Agency will meet with manufacturers, processors and other interested parties for the purpose of attempting to negotiate a consent agreement. To facilitate attendance at these meetings, EPA will contact all interested parties who have expressed a desire to participate in or monitor negotiations under paragraph (b)(2) of this section and advise them of meeting dates.

(4) All negotiating meetings will be open to members of the public. The minutes of each meeting will be prepared by EPA. Meeting minutes, testing proposals, background documents and other materials exchanged at or prepared for negotiating meetings will be included in the public file established by EPA on each ITC-recommended chemical. Materials in this file will be made available for inspection in the OPTS Reading Room during EPA working hours.

(5) While negotiations are underway, EPA will promptly circulate meeting minutes, testing proposals, correspondence and other relevant materials to interested parties who expressed a desire to participate in or monitor negotiations pursuant to paragraph (b)(2) of this section.

(6) As negotiations progress, EPA will make a tentative decision either to proceed with formulation of a consent agreement or to initiate rulemaking. EPA will terminate negotiations after 10 weeks and proceed with rulemaking unless negotiations are likely to result in a draft consent agreement within 4 additional weeks. By the end of this 4-week period, EPA either will have prepared a draft consent agreement reflecting the apparent consensus of the parties or will terminate negotiations and proceed with rulemaking. If EPA decides to proceed with rulemaking, no further opportunity for negotiations will be provided. EPA will promptly send written notice to all interested parties of the termination of negotiations.

(7) Where EPA prepares a draft consent agreement, it will be circulated for comment to all interested parties who expressed a desire to participate in or monitor negotiations under paragraph (b)(2) of this section. A period of 4 weeks will be provided for submitting comments or written objections under § 790.24(a).

(8) If necessary, EPA will hold a public meeting to discuss comments on the draft consent agreement and to determine whether revisions in the agreement are appropriate.

(9) Where a consensus exists concerning the contents of a draft consent agreement, it will be circulated to EPA management and interested parties for final approval and signature.

(10) Upon final approval of a consent agreement, EPA will public a **Federal Register** notice that summarizes the agreement, describes the ITC recommendations for the test substance, outlines the chemical's use and exposure characteristics, and explains the background, objectives and rationale of the testing to be conducted, and codifies in subpart C of Part 799 the name of the substance(s) to be tested and the citation to the **Federal Register** notice of the agreement.

§ 790.24 Criteria for determining whether a consensus exists concerning the provisions of a draft consent agreement.

(a) EPA will enter into consent agreements only where there is a consensus among the Agency, one or more manufacturers and/or processors who agree to conduct or sponsor the testing, and all other interested parties who identify themselves in accordance with § 790.22(b)(2). EPA will not enter into a consent agreement in either of the following circumstances:

(1) EPA and affected manufacturers and/or processors cannot reach a consensus on the testing requirements or other provisions to be included in the consent agreement.

(2) A draft consent agreement is considered inadequate by other interested parties who, pursuant to § 790.22(b)(2), have asked to participate in or monitor negotiations; and these parties have submitted timely written objections to the draft consent agreement which provide a specific explanation of the grounds on which the draft agreement is objectionable.

(b) EPA may reject objections described in paragraph (a)(2) of this section only where the Agency concludes the objections are either:

(1) Not made in good faith.

(2) Untimely.

(3) Do not involve the adequacy of the proposed testing program or other features of the agreement that may affect EPA's ability to fulfill the goals and purposes of the Act.

(4) Not accompanied by a specific explanation of the grounds on which the

draft agreement is considered objectionable.

(c) The unwillingness of some manufacturers and/or processors of a prospective test chemical to sign the draft consent agreement does not, in itself, establish a lack of consensus if EPA concludes that those manufacturers and/or processors who are prepared to sign the agreement are capable of accomplishing the testing to be required and that the draft agreement will achieve the purposes of the Act in all other respects.

§ 790.26 Initiation and completion of rulemaking proceedings on ITC-designated chemicals.

(a) Where EPA concludes that a consensus does not exist concerning the provisions of a draft consent agreement and that the findings specified by section 4(a) can be made, the Agency will proceed with rulemaking under section 4(a) of TSCA.

(b) When EPA decides to proceed with rulemaking under paragraph (a) of this section, the Agency intends to publish a rulemaking proposal and a final rule or a notice terminating the rulemaking proceeding in accordance with the schedule specified in Appendix A to this Part.

(c) Where the testing recommendations of the ITC raise unusually complex and novel issues that require additional Agency review and opportunity for public comment, the Agency may publish an Advance Notice of Proposed Rulemaking (ANPR). The schedule that EPA intends to follow for rulemaking proceedings initiated by publication of an ANPR is presented in Appendix A to this Part.

§ 790.28 Procedures for developing consent agreements and/or test rules for chemicals that have not been designated or recommended with intent to designate by the ITC.

(a) Where EPA believes that testing is needed, it may also develop consent agreements and/or test rules on chemical substances or mixtures that either:

(1) Have been recommended but not "recommended with intent to designate" by the ITC.

(2) Have been selected for testing consideration by EPA on its own initiative.

(b) When EPA wishes to initiate negotiations concerning chemicals described in paragraph (a) of this section, it will publish a **Federal Register** notice describing its tentative evaluation of testing needs, announcing a date for a public course-setting meeting, and inviting persons interested in participating in or monitoring negotiations to contact the Agency in writing. Any negotiations that EPA conducts will conform to the procedures specified in § 790.22(b) and, to the extent feasible, will follow the schedules presented in Appendix A to this Part.

(c) EPA will enter into consent agreements on chemicals described in paragraph (a) of this section only if there is a consensus among EPA, affected manufacturers and/or processors, and any other persons who have asked to participate in or monitor negotiations. In determining whether such a consensus exists, EPA will employ the criteria specified in § 790.24. In the absence of consensus, EPA will initiate rulemaking if it concludes that the findings specified in section 4(a) of the Act can be made. The schedule for initiating and completing such rulemaking proceedings will, to the extent feasible, follow the schedule specified in Appendix A to this Part.

* * * * * *

e. By adding Subpart D, to read as follows:

Subpart D—Implementation, Enforcement and Modification of Consent Agreements

Sec.

Subpart D—Implementation, Enforcement and Modification of Consent Agreements

§ 790.60 Contents of consent agreements.

(a) *Standard provisions.* All consent agreements will contain the following provisions:

(1) Identification of the chemical(s) to be tested.

(2) The health effects, environmental effects and/or other characteristics for which testing will be required.

(3) The names and addresses of each manufacturer and/or processor who will sign the agreement.

(4) The name and address of the manufacturer, processor or other entity who has agreed to act as the principal test sponsor.

(5) The technical or commercial grade, level of purity or other characteristics of the test substances(s) or mixture(s).

(6) Standards for the development of test data.

(7) A requirement that testing will be conducted in accordance with the EPA Good Laboratory Practice (GLP) regulations (40 CFR Part 792).

(8) Schedules with reasonable timetables and deadlines for initiating testing and submitting interim progress and/or final reports to EPA.

(9) A requirement that the principal sponsor will submit a study plan to EPA in accordance with § 790.62.

(10) A statement that the results of testing conducted pursuant to the consent agreement will be announced to the public in accordance with the procedures specified in section 4(d) of the Act and that the disclosure of data generated by such testing will be governed by section 14(b) of the Act.

(11) A requirement that the manufacturers and/or processors signing the consent agreement will comply with the notification requirements of section 12(b)(1) of the Act and Part 707 of this Chapter if they export or intend to export the substance or mixture for which the submission of data is required under the agreement and a statement that any other person who exports or intends to export such substance or mixture is subject to the above cited export notification requirements.

(12) A requirement that, in the event EPA promulgates a significant new use rule applicable to the test chemical under section 5(a)(2), the consent agreement will have the status of a test rule for purposes of section 5(b)(1)(A) and manufacturers and/or processors signing the agreement will comply with the data submission requirements imposed by that provision.

(13) A statement that each manufacturer and/or processor signing the agreement agrees that violation of its requirements will constitute a "prohibited act" under section 15(1) of the Act and will trigger all provisions of TSCA applicable to a violation of section 15.

(14) A statement that, in the event one or more provisions of the agreement are determined to be unenforceable by a court, the remainder of the agreement would not be presumed to be valid and EPA will then either initiate a rulemaking proceeding or publish in the **Federal Register** the Administrator's reason for not initiating such a proceeding.

(15) A statement that the Agency may conduct laboratory inspections and/or study audits of the testing being conducted pursuant to the consent agreement in accordance with the authority and procedures contained in section 11 of the Act.

(16) A statement that EPA acceptance of a consent agreement constitutes "final agency action" for purposes of 5 U.S.C. 704.

(17) Any other requirements that the parties agree are necessary to achieve the purposes of the Act.

(b) *Contents of standards for the development of data.* The standards for the development of the data included in consent agreements will be based on the TSCA test guidelines in 40 CFR Parts 796, 797, and 798, the Organization for Economic Cooperation and Development (OECD) test guidelines, the EPA pesticide assessment guidelines published by The National Technical Information Service (NTIS), or other suitable test methodologies. During the negotiation of consent agreements, EPA will initially propose suitable test guidelines as the required test standards; manufacturers and processors or other interested parties may then suggest alternative methodologies or modifications to the Agency's proposed guidelines. These alternative methodologies or modifications will be adopted only where, in the judgment of EPA, they will develop at least equally reliable and adequate data on the chemical substance or mixture subject to the agreement.

(c) *Statement of rationale for consent agreement.* EPA will prepare a written explanation of the basis for each consent agreement. This document will summarize the agreement, describe any ITC testing recommendations for the chemical involved, outline the chemical's use and exposure characteristics, and explain the objectives of the testing to be conducted and the rationale for the specific studies selected. This document will be published in the **Federal Register** and, for ITC-designated chemicals, will constitute the statement of EPA's reasons for not initiating rulemaking required by section 4(e)(1)(B) of the Act.

§ 790.62 Submission of study plans and conduct of testing.

(a) *Timing of submission.* The principal sponsor of testing conducted pursuant to a consent agreement shall submit a study plan no later than 45 days prior to the initiation of testing. The Agency may grant requests for additional time to submit study plans on a case-by-case basis. Requests for additional time for study plan development must be made in writing to the Director, Office of Compliance Monitoring (EN-342), Office of Pesticides and Toxic Substances, EPA, 401 M Street, SW., Washington, DC 20460. Each extension request must demonstrate why the extension should be granted. EPA will notify the submitter by certified mail of the Agency's decision to grant or deny any extension request. Extensions of time for submission of study plans granted by EPA will not relieve manufacturers and/or processors of the obligation to meet the consent agreement's schedule for initiating testing and submitting interim and/or final reports.

(b) *Content of study plans.* All study plans are required to contain the following information:

(1) Identity of the consent agreement under which testing will be performed.

(2) The specific test requirements to be covered by the study plan.

(3) The name and address of the principal test sponsor.

(4) The names, addresses, and telephone numbers of the responsible administrative official[s] and project manager[s] in the principal sponsor's organization.

(5) The names, addresses, and telephone numbers of the technical contacts at each manufacturer and/or processor subject to the agreement.

(6) The names and addresses of the testing facilities responsible for the testing and the names, addresses, and telephone numbers of the administrative officials[s] and project manager[s] assigned to oversee the testing program at these facilities.

(7) Brief summaries of the training and experience of each professional involved in the study, including study director, veterinarian[s], toxicologist[s], pathologist[s], chemist[s], microbiologist[s], and laboratory assistants.

(8) Identity and supporting data on the chemical substance[s] being tested, including physical constants, spectral data, chemical analysis, and stability under test and storage conditions, as appropriate.

(9) Study protocol, including rationale for species/strain/sex selection; dose selection (and supporting data); route[s] or method[s] and form[s] and duration of exposure; description of diet to be used and its source, including nutrients and contaminants and their concentrations; description of the controls; for *in vitro* test systems, a description of culture medium and its source; and a summary of expected spontaneous chronic diseases (including tumors), genealogy, and life span.

(10) A schedule, with reasonable timeables and deadlines, for initiation and completion of each short-term test and of each major phases of long-term tests, and submission of interim progress and/or final reports to EPA.

(c) *Review and modification.* (1) Upon receipt of a study plan, EPA will review it to determine whether it complies with paragraph (b) of this section and the consent agreement. If EPA determines that the study plan does not comply with paragraph (b) of this section, EPA will notify the submitter that the submission is incomplete and will identify the deficiencies and the steps necessary to complete the submission.

(2) The submitter will have 15 days after the day it receives a notice under paragraph (c)(1) of this section to submit appropriate information to make the study plan complete.

(3) If the submitter fails to provide appropriate information to complete a study plan within 15 days after having received a notice under paragraph (c)(1) of this section, the submitter will be considered to be in violation of the consent agreement and subject to enforcement proceedings pursuant to § 790.65 (c) and (d).

(d) *Functions of the principal test sponsor.* When testing is being conducted pursuant to a consent agreement, the principal test sponsor will be responsible for submitting interim progress and final reports to EPA, informing the Agency of any proposed changes in standards for the development of data, study plans or testing schedules, and communicating with the Agency about laboratory inspections and other matters affecting the progress of testing.

§ 790.65 Failure to comply with a consent agreement.

(a) Manufacturers and/or processors who have signed a consent agreement and who fail to comply with the test requirements, test standards, GLP regulations, schedules, or other provisions contained in the consent agreement, or in modifications to the agreement adopted pursuant to § 790.68, will be in violation of the consent agreement.

(b) The Agency considers failure to comply with any aspect of a consent agreement to be a "prohibited act" under section 15 of TSCA, subject to all of the provisions of the Act applicable to violations of section 15. Section 15(1) of TSCA makes it unlawful for any person to fail or refuse to comply with any rule or order issued under section 4. Consent agreements adopted pursuant to this part are "orders issued under section 4" for purposes of section 15(1) of TSCA.

(c) Manufacturers and/or processors who violate consent agreements are subject to criminal and/or civil liability. Under the penalty provisions of section 16 of TSCA, such firms could be subject to a civil penalty of up to $25,000 per violation with each day in violation constituting a separate violation of section 15. Intentional violations could

lead to the imposition of criminal penalties of up to $25,000 for each day of violation and imprisonment for up to one year. In addition, EPA could invoke the remedies available under section 17 of TSCA, including seeking an injunction to compel adherence to the requirements of the consent agreement.

(d) Noncompliance with a consent agreement will constitute conduct "in violation of this Act" under section 20(a)(1) of TSCA. Thus, failure to comply with the requirements of a consent agreement could result in a citizens' civil action under section 20(a)(1) of TSCA.

§ 790.68 Modification of consent agreements.

(a) *Changes in the scope of testing.* (1) Manufacturers or processors subject to a consent agreement, other persons or EPA may seek modifications in the scope of testing performed under the consent agreement. If, upon receiving a request for modification, EPA determines that new issues have been raised that warrant reconsideration of the scope of testing, or if EPA determines on its own that such reconsideration is appropriate, EPA will publish a **Federal Register** notice describing the proposed modification and soliciting public comment. If, based on the comments received, EPA concludes that differences of opinion may exist about the proposed modification, EPA will establish a schedule for conducting negotiations and invite parties who wish to participate in or monitor these negotiations to contact the Agency in writing. Any negotiations that EPA conducts will conform to the procedures specified in § 790.22(b).

(2) The scope of testing required by a consent agreement will be modified only where there is a consensus concerning the modified testing requirements among EPA, affected manufacturers and/or processors, and other persons who have asked to participate in or monitor negotiations under paragraph (a)(1) of this section. In determining whether a consensus exists, EPA will employ the criteria specified in § 790.24. In the absence of consensus, EPA may initiate rulemaking under section 4(a) of the Act if it concludes that any testing beyond that required by the consent agreement is necessary and that the other statutory findings required by section 4(a) can be made. While such rulemaking proceedings are underway, the consent agreement will remain in effect unless EPA finds that the testing required by the agreement is or may be unnecessary in view of the testing requirements included in EPA's proposed rule.

(b) *Changes in test standards or schedules.* (1) Any test sponsor who wishes to modify the test standards or schedules for any test required under a consent agreement must submit an application in accordance with this subsection. Applications for modification must be made in writing to the Director, Office of Compliance Monitoring (EN-342), Office of Pesticides and Toxic Substances, EPA, 401 M Street, SW., Washington, DC 20460, or by phone, with written confirmation to follow within 10 working days. Applications must include an appropriate explanation of why the modification is necessary.

(2) EPA will seek public comment on all substantive changes in test standards and schedules. EPA will issue a notice in the **Federal Register** requesting comments on requested modifications. However, EPA will act on the requested modification without seeking public comment if either:

(i) EPA believes that an immediate modification to a test standard or schedule is necessary to preserve the accuracy or validity of an ongoing study.

(ii) EPA determines that a modification clearly does not pose any substantive issues.

(3) EPA will notify the sponsor of EPA's approval or disapproval. When EPA approves a modification, the parties will enter into a modified consent agreement. EPA will publish a notice in the **Federal Register** announcing that the test standard or schedule has been modified, describing the nature of the modification.

f. By revising the heading of Subpart E, to read as follows:

Subpart E—Exemptions From Test Rules

g. By adding Appendix A to Subpart E, to read as follows:

Appendix A to Subpart E—Schedule for Developing Consent Agreements and Test Rules

EPA intends to follow the schedule set forth in this Appendix to evaluate testing candidates, conduct negotiations, develop consent agreements where appropriate, and propose and promulate test rules in those instances where testing can be required under section 4(a) of TSCA but agreement cannot be reached in timely manner on a consent agreement. Where deadlines are imposed by the statute, they are binding on EPA and will be observed by the Agency. The remaining dates represent targets that EPA intends to meet.

This schedule is based on what EPA currently believes are reasonable target dates. As EPA gains experience with the process and determines the feasibility of these schedules, it may adjust the schedule accordingly. EPA will solicit public comment before implementing any changes in the schedule.

Week [1]	Event
0	Receive ITC report, recommendation.
2	Publish ITC report, 8(a) & 8(d) notices, and invitation for public participation in negotiations.
3-6	Comment period on ITC report.
6	Public focus meeting.
7-14	8(a) and 8(d) reporting period.
22	Public meeting on course-setting decision and deadline for requests to participate in negotiations.
22-30	Negotiations.
32	EPA decision point: consent agreement or test rule.

[1] The dates contained in the left-hand column are calculated from the date EPA receives the ITC report recommending a chemical for testing.

Week	Consent Agreement	Week	Test Rule
36-40	Comment period on consent agreement	32-60	Rule preparation, agency review and sign-off.
42	Comment resolution meeting if necessary	62	Publish proposed rule in **Federal Register**.[1]
46	Sign-off consent agreement and **Federal Register** notice	70-106	Agency reviews comments; preparation of final rule or no-test decision, agency review and sign-off.[1]
50	Publish **Federal Register** notice	108	Publish final rule or no-test decisoin in **Federal Register**.[1]

[1] As stated in § 790.26, EPA may publish an Advance Notice of Proposed Rulemaking (ANPR) where the testing recommendations of the ITC raise unusually novel and complex issues that require additional Agency review and opportunity for public comment. EPA intends to publish such ANPRs by Week 62 following receipt of the initial ITC report; to publish a proposed rule or decision-not-to-test by Week 108; and to publish a final rule or notice terminating the rulemaking process by Week 154.

PART 799—[AMENDED]

2. Part 799 is amended as follows:

a. The authority citation for Part 799 continues to read as follows:

Authority: 15 U.S.C. 2603, 2611, 2625.

b. By adding § 799.19 to Subpart A, to read as follows:

§ 799.19 Chemical imports and exports.

Persons who export or who intend to export substances listed in Subpart B or Subpart C of this part are subject to the requirements of Part 707 of this title.

c. By adding and reserving Subpart C as follows:

Subpart C—Consent Testing Agreements [Reserved]

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